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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

MAILED

Application Number: 09/938,294
Filing Date: August 24, 2001
Appellant(s): HINKLE ET AL.

AUG 12 2004

GROUP

Thomas E. Holsten et al.
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed June 1, 2004.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows: in Appellant's 6(a), it should read: whether claims 1-5, 8-10 and 14-18 are unpatentable under 35 U.S.C. § 101 for allegedly being unsupported by a specific, substantial asserted utility or a well established utility.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 1-3, 8, 14 and 15 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) ClaimsAppealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10) *Grounds of Rejection*

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-5, 8-10 and 14-18 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial asserted utility or a well established utility. The claims are directed to a nucleic acid molecule having 90-100% sequence identity with SEQ ID NO:2, a nucleic acid molecule encoding the amino acid sequence of SEQ ID NO:45, and transformed cell, plant or organism containing said nucleic acid molecules. The specification disclosed that the claimed invention could be used “to develop nutritionally and agriculturally enhanced crops and products” and “aid gene expression studies that allow the dissection and elucidation of commercially useful traits” (p. 2, lines 1-6). The specification does not disclose any trait the claimed invention can be used to enhance, or how the claimed invention can be used to enhance such trait. Under current utility guidelines, the claimed invention lacks specific and substantial asserted utility for the following reasons. First of all, if a plant gene affects plant growth or development in any way, positively or adversely, then the gene is directly or indirectly involved in “nutritionally and agriculturally enhanced crops and products”. Thus this asserted utility is not specific to any particular class or group of plant genes, as most if not all plant genes would fulfill this asserted utility. It should be noted here that Appellant does not disclose the function of the claimed nucleic acid

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molecule or how it would benefit the plant. Secondly, the claimed invention lacks substantial utility because a utility which requires or constitutes carrying out further research to identify or reasonably confirm a real world context of use is not a substantial utility. In *Brenner v. Manson*, the court established:

“The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point--where specific benefit exists in currently available form--there is insufficient justification for permitting an Appellant to engross what may prove to be a broad field.” (*Brenner v. Manson*, 383 U.S. 519 (1966)).

Thus, while commercially useful traits such as increased yields would provide substantial benefit to the public, it is unclear how one of ordinary skill in the art would be able to use SEQ ID NO:2 encoding SEQ ID NO:45 “to develop nutritionally and agriculturally enhanced crops and products” and “aid gene expression studies that allow the dissection and elucidation of commercially useful traits” as set forth in the specification. It is unclear what trait is correlated with the claimed sequence, or how said sequence should be used to enhance said trait. Should the expression or SEQ ID NO:2 be increased, decreased or inhibited to enhance the plant’s nutritional value or commercially useful trait? Which trait(s)? Accordingly, the claimed invention lacks specific and substantial utility. Note, because the claimed invention is not supported by a specific, substantial asserted utility for the reasons set forth above, credibility cannot be assessed.

In addressing well-established utility, since the claimed invention lacks asserted utility for the reasons set forth above, the claimed invention also lacks well-established utility, such as probes and primers for use in hybridization assays. While one skilled in

the art can readily generate probes and primers from the claimed sequence, it is unclear how probes and primers of a gene of undisclosed function would be useful to the public. Accordingly, the claimed invention also lacks well-established utility.

Claims 1-5, 8-10 and newly added claims 14-18 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The rejection of claims 1-5 and 8-10 and 14-18 under 35 U.S.C. 112, second paragraph has been withdrawn. “Substantially purified” is defined as a molecule separated from substantially all other molecules normally associated with it in its native state (p. 8, lines 20-21 of the specification). A “structural nucleic acid molecule” is defined as encoding a protein comprising an amino acid sequence of SEQ ID NO:45 (Brief, p. 16).

(11) Response to Argument

Appellant traverses, stating that 1) “to develop nutritionally and agriculturally enhanced crops and products” and “aid gene expression studies that allow the dissection and elucidation of commercially useful traits” comply with the utility requirements; and 2) the uses set forth are analogous to a microscope and golf club in that a utility generic to a broad class of molecules does not compromise the specific utility of an individual member of that class (Arguments filed 10/14/03, p.7 and Brief, p. 9).

Appellant's traversals have been considered but are deemed unpersuasive for the following reasons. While all microscopes and golf clubs have a well-established utility, Appellant's gene sequence of unknown function does not have a well-established utility. Thus, Appellant's asserted utility must be assessed. For a claimed invention to have asserted utility under current utility guidelines, its asserted utility must be credible, specific and substantial. As stated in the previous Office actions of record and above, the claimed invention fails to meet the specific and substantial requirements. That is, Appellant's gene does not belong in a specific class of genes (for example, a gene encoding a phosphorylase enzyme); and the use set forth is not deemed to be sufficiently substantial such that one skilled in the art can readily use the invention in a real-world sense (for example, expression of the gene renders the plant disease resistant). One phosphorylase gene does not negate the utility of another phosphorylase gene; and likewise, one disease resistance gene does not negate the utility of another disease resistance gene. Such is not the case here. Appellant's gene is not specific to any particular class –to say that a gene belongs to the gene class does not define the class of genes. Further, not all genes have utility because the functions of many genes are not known, or no substantial benefit has been correlated with them. In contrast, substantial benefits have been correlated with microscopes and golf clubs, and their usefulness does not need further elaboration here. Thus Appellant's invention cannot be equated with microscopes and golf clubs. One skilled in the art would not be able to use Appellant's invention to achieve real-world benefits without further research.

When a claimed invention lacks specific and substantial utility, the credibility requirement of utility cannot be assessed.

In the Brief, Appellant further traverses that a single utility alone is enough to satisfy Section 101, and the claimed invention provides identifiable benefits: to identify the presence or absence of a polymorphism, as a probe for monitoring gene expression, for isolating a variety of genes, to measure the level of mRNA in a sample, as molecular markers, promoters, transcriptional regulatory elements and in cosuppression or antisense expression constructs (Brief, p. 5-6).

This traversal also fails to persuade for the following reasons. It is true that only a single utility is necessary to satisfy Section 101, but the utility must be credible, specific and substantial. Here none of Appellant's utilities meets the specific and substantial requirements. The uses disclosed by Appellant are not specifically limited to any particular gene or class of genes but would apply to all nucleic acid molecules. Additionally, the identifiable benefits must allow one skilled in the art to achieve practical, real-world benefits in its current available form. Identifying the presence or absence of a polymorphism is not limited to any particular class of genes, but would be applicable to all genes, their fragments, as well as random polynucleotide sequences. Further, Appellant has not shown polymorphisms exist for the claimed invention, or how determining polymorphisms for the claimed invention would be of use. Similarly, probes and primers can be obtained for all genes to monitor gene expression or to isolate a gene: what is missing is the correlation between gene expression or the gene isolated using Appellant's probe/primer and some real-world usefulness. With regard to

measuring the level of mRNA in a sample, unless the significance of detecting the mRNA is known or disclosed—because of some correlation between its expression and some useful trait—such measuring is meaningless without further research. The specification does not disclose how to interpret the data obtained from measuring the level of mRNA in a sample. Similarly, using Appellant's invention as molecular markers lacks specific utility because any orphan polynucleotide can be used in the same way. While the utility of promoters and certain transcriptional regulatory elements is well-established, Appellant has not shown that the claimed nucleic acid molecule is a promoter or regulatory element, that the claimed invention can be used to identify promoters and regulatory elements, or how this can be achieved using the claimed nucleic acid molecule. Moreover, there is no specific relationship between Appellant's polynucleotide and a promoter or regulatory element that other nucleic acid molecules of other genes do not possess. With regard to cosuppression or antisense expression constructs, again, without knowing what useful trait is correlated with cosuppression or antisense expression of Appellant's nucleic acid molecule, one skilled in the art would not know how these constructs would be of practical benefit in accordance with Brenner. Specific benefit does not exist in currently available form. All utilities put forth by Appellant would be applicable to all nucleic acid molecules. Furthermore, patentability of the claimed invention would pre-empt another from taking the claimed nucleic acid molecule and determine a useful function or correlate it with something useful to benefit the general public. This is precisely the concern of the Brenner Court, which states, “[A] process patent in the chemical field, which has not been developed

and pointed to the degree of specific utility, creates a monopoly of knowledge which should be granted only if clearly commanded by the statute. Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development." (Brenner, 383 U.S. at 534, 148 USPPQ at 695).

The claimed nucleic acid molecule cannot be equated with a microscope, a gas chromatograph or a golf club as put forth by Appellant in the Brief, as their uses are well-established and they meet the credible, specific and substantial requirements. Nucleic acid molecules do not have well-established uses. Therefore, if the asserted uses fail to meet any one of the three requirements, it would lack utility. One skilled in the art would know what to do with the information obtained from a microscope, for example. If the microscope was used to identify whether the bacteria are gram-positive or gram-negative, then proper antibiotics can be administered to a patient in need thereof. In contrast, one skilled in the art would not know what to do with the information obtained from Appellant's invention. Accordingly, the claimed invention lacks utility under the current utility guidelines (Utility Examination Guidelines published in Federal Register/ Vol. 66, No. 4/ Friday, January 5, 2001/ Notices; p. 1092-1099).

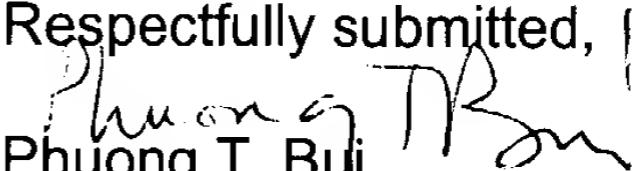
Because the claimed invention is not supported by either a specific, substantial asserted utility or a well-established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Thus, the 35 U.S.C

112, first paragraph rejection is maintained for the reasons set forth in the utility rejection above.

Appellant traverses that it is well-established law that "the enablement requirement is met if the description enables any mode of making and using the invention" (Brief, p. 14).

While the Office concedes that one skilled in the art can readily *make* the invention, one skilled in the art would not know how to *use* the invention.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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ptb
August 7, 2004

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